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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,272	12/19/2000	Charles Raymond Degenhardt	8371	6508

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EXAMINER

MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,272

Applicant(s)

DEGENHARDT ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,9,11,19-25,27-31 and 59 is/are pending in the application.

4a) Of the above claim(s) 9 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 2,4,18-23,25,27,29 and 30 is/are rejected.

- 7) ☒ Claim(s) 24,28 and 31 is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to amendments filed on 1/7/03. Applicants have amended claims 18 and 29-31. Applicants have cancelled claims 5 and 26. Objection was made in the previous action to claims 24 and 28. All other claims were rejected. There are seventeen claims pending and sixteen under consideration. Claims 2, 4, 9, 11, and 18-24 are compound claims. Claims 25, 27, and 28 are composition claims. Claims 29-31 are use claims. This is the fourth action on the merits. The application concerns some 2-heterocyclylcarbonyl-piperidines.

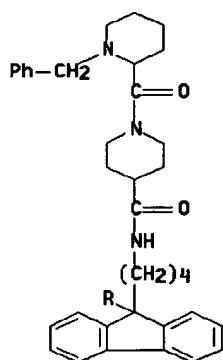
Response to Amendments and Arguments

2. Applicants' claim cancellation renders moot the objection made in point #7. Applicants limiting claims 29-31 to treatment of multidrug resistance overcomes the indefiniteness rejection made in point #9. Applicants' deletion of amides *etc.* overcomes the enablement rejection made in point #10. Applicants' proviso concerning the relationship between R^4 and variable r overcomes the art rejection over Xue (WO 99/65,867) made in point #12. However, that proviso constitutes new matter. Please see point #5 below. Applicants' argument concerning Sato ('239) is persuasive. Applicant has limited the ring formed by R^2 and R^3 in claim 18 to be a substituted piperidine. In lines 10-14, page 6 Applicants define a substituted heterocyclic group. Piperidine is a heterocyclic group and the

piperidine ring of the compound taught by Sato ('239) is not substituted. Thus, the art rejection made in point #13 is withdrawn. The requirement that the piperidine ring be substituted is made in parent claim 18, not in dependant claim 4, as indicated in the previous office action. The Examiner regrets the error. Applicants deletion of $R^4 = SO_2$ as claimed subject matter overcomes the art rejection made in point #14.

Election/Restrictions

3. The elected species is compound number 7, on page 34 and is also the first pictured compound in claim 24. The elected species has $x = 0$, the piperidine ring formed by R^2 and R^3 substituted by an amide group, $R^4 = CH(R^1)$, $R^1 = \text{hydrogen}$, $t = 2$, with one independent $R^1 = \text{hydroxyl}$, $r = 1$, and $R^6 = 5\text{-quinolinyl}$. Applicants amended their claims to delete $R^4 = SO_2$. Following the procedure specified in MPEP §803.02 the search was expanded and the following compound located in



Biller (WO 97/26240 A1). It fits the formula of claim 18 with $R^5 = O_rR^6$, $r = 0$, $R^6 = \text{the aromatic group phenyl}$, $t = 0$, $R^4 = CH(R^1)$, $R^1 = \text{hydrogen}$, $A = \text{piperidine}$, w

= 0, and $\text{NR}^2\text{R}^3 = 9\text{H-fluoren-9-yl]butyl 4-piperidecarboxamide}$. The compound is pictured at the bottom of page 592. The compound is excluded by Applicants proviso requiring the presence of an oxygen atom in R^5 when R^4 is a carbon. However, that proviso is new matter and the Examiner has met his burden concerning expansion of the search. Claim 9 remains withdrawn from consideration since it is drawn to different R^4 group than that of the elected species.

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 2, 4, 11, 18-23, 25, 27, 29, and 30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "about 10", "about 4", and "about 9" in claim 18 are indefinite. The ring A must contain a positive whole number of members. Does "about 10" mean ten atoms or could it mean eleven? How about fifteen?

Applicants continue to argue that "about" is an acceptable term in chemical patents. Applicants make three arguments. Firstly, they cite *W.L. Gore & Associates Inc. v. Garlock Inc.* (CA FC) 6 USPQ2d 1277, *Pall Corp. v. Micron Separations Inc.* (CA FC) 36 USPQ2d 1225, and *Modine Manufacturing Co. v. U.S. International Trade Commission* (CA FC) 37 USPQ2d 1609. Secondly,

Applicants correctly note that that the term "about" in reference to atom count occurs in issued US Patents. Thirdly, Applicants allege that an Examiner is not competent to reject the word about, only a court may do so.

Firstly, the three case cited by Applicants maybe distinguished from the present situation on both legal and factual grounds. The legal question in the three cites was that of interference not, the indefiniteness issue in the present application. In all three cases the word "about" modified a continuous variable, not the discrete variable that is an atom count. The variable being modified in all three cases could be varied by any small amount desired. In the present situation, it may not. The laws of chemistry permit only whole numbers of atoms. In *W.L. Gore & Associates Inc. v. Garlock Inc.* (CA FC) 6 USPQ2d 1277 the word modified a rate of stretching measured as a percentage. The court holding that "[w]hether an imprecise claim limitation, such as the phrase "about 100% per second" is literally met, is a question of fact for the trial court. See *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 829, 221 USPQ 568, 576 (Fed. Cir. 1984) (scope of term "substantially equal to" determined by trier of fact). A term such as "about" is not subject to such a precise construction as Gore would give it, but is dependent on the factual situation presented." In *Pall Corp. v. Micron Separations Inc.* (CA FC) 36 USPQ2d 1225 the word modified a "ratio CH₂:NHCO of

methylene CH₂ to amide NHCO groups". The court holding that "[t]he use of the word "about," avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context." In *Modine Manufacturing Co. v. U.S. International Trade Commission* (CA FC) 37 USPQ2d 1609 the word modified the diameter of a tube in an air conditioning condenser. The court held that "[t]he specification uses the qualifier "about", and also states that the optimum hydraulic diameter varies with the conditions. Such broadening usages as "about" must be given reasonable scope; they must be viewed by the decision-maker as they would be understood by persons experienced in the field of the invention."

The experienced chemist would understand that about ten atoms could only mean ten atoms. She would understand that atoms occur in whole units only. The possibility that it might mean eleven atoms would be as equally remote as the possibility that it means only nine atoms maximum or that it means fifteen atoms.

Secondly, the indefiniteness remains despite what was allowed in another case. The U.S. Court of Customs and Patent Appeals wrote *In re Giolito* 188 USPQ 645: "We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others. See *In re Margaroli*, 50 CCPA 1400,

318 F.2d 348, 138 USPQ 158 (1963); *In re Wright*, 45 CCPA 1005, 256 F.2d 583, 118 USPQ 287 (1958); *In re Launder*, 41 CCPA 887, 212 F.2d 603, 101 USPQ 391 (1954)".

The Examiner in the previous action raised a question regarding the number of atoms intended by the word about. Applicants clarified that 9.9 or 10.1 atoms was not intended. The Examiner also asked eleven or fifteen was included in the phrase about ten. If applicants cannot answer the question how then is the public to determine intended scope?

Thirdly, the courts have clarified that the meaning of "about" is a factual question and depends upon the scientific situation. Why then, is the Examiner precluded from raising the issue of its' meaning in this Application? As stated by *In re Zletz*, 13 USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." The phrase "about 10" atoms is ambiguous.

The Examiner suggests removing the word.

5. Claims 2, 4, 11, 18-23, 25, 27, 29, and 30 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The proviso in the last line of section (f) of claim 18, concerning the relationship between R^4 and R^5 and requiring the presence of an oxygen atom in R^5 when R^4 is a carbon atom lacks description. Nowhere in the specification is such a relationship linking the description between the two radicals described. The concept of linking the value of r to the specific divalent radical present as R^4 is not present. Such a negative limitation requires description. In *Ex parte Grasselli, et al.* 231 USPQ 393, decided June 30, 1983, the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences said: "we agree with the examiner's position of record that the negative limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112." "It might be added that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts."

Applicants point to Example 7, the elected species, as supportive of their proviso and argue that verbatim support is not required for the proviso. Concerning the Example 7, it certainly fits within the proviso, since it contains the extra oxygen atom required when R^4 is carbon. The Examiner agrees that a

verbatim recitation of the proviso is not required, only that an unequivocal indication that Applicants possessed the concept embraced by the proviso was present at the time of filing. The test is whether the average chemist, looking at the formula of Example 7 would immediately recognize that R^5 must always contain oxygen when R^4 is carbon. Why not conclude that R^6 must be a 5-quinoline group or that x must be 0, or that t must be 2, or that w must be 0, or that A must be a piperidine ring, or that the substituent on the ring formed by R^2 and R^3 is the complex amide function of Example 7? These are also characteristics of Example 7. What guideposts direct the average chemist to see the complex relationship between variables required by the proviso as she looks at the formula? Why is the average chemist to conclude that only one of the relationships among structural elements is implied by the structural formula is now present? Until the Examiner found art anticipating Applicants claims, Applicants made no assertion and did not appear to recognize that there was any such relationship among variables R^4 and R^5 .

The Examiner suggests requiring variable r to be 1 independently of the status of variable R^4 . Such an amendment would give a genus incorporating all of Applicants working examples and such an amendment, limiting the elements of a Markush list, is clearly allowable by the case law.

Allowable Subject Matter

6. Claims 24, 28, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for after final amendments is (703) 872-9307. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the

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Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

TCMcK
March 17, 2003



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